DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Vista Medical Technologies
Mr. Graham A.L. Baillie
Manager, Quality Assurance and Service
134 Flanders Road
Westborough, MA 01581

JUL 27 2015

Re: K020301
Trade/Device Name: Vista Stereoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, GCJ
Dated (Date on orig SE ltr): January 28, 2002
Received (Date on orig SE ltr): January 29, 2002

Dear Mr. Baillie,

This letter corrects our substantially equivalent letter of February 12, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

11) Indications for Use Statement

Statement of Intended Use

510(k) Number (if Known): K020301

Device Name: **Vista Stereoscope System**

Indications For Use:

The Vista StereoScope System is intended for the use in endoscopic procedures and all types o video assisted procedures, including general endoscopic and laparoscopic, thoracic, anterior an posterior spinal and as an aid in visualization of cardiac structures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE I NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use (Optional Format 1-2-96)**

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020301

K020301

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VISTA Medical Technologies

9) 510(k) Summary

510(k) Summary for Vista Stereoscope System

A. Sponsor

Vista Medical Technologies
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B. Contact Name

Graham A. L. Baillie
Manager,
Quality Assurance and Service
Vista Medical Technologies
Phone: (508) 366-3668 ext. 8279
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C. Device Name

Vista Stereoscope System

D. Predicate Device(s)

Vista Stereoscope System (K990635); Vista Single Chip Video Camera (K971373)

E. Device Description

The Vista StereoScope System is a device used to allow observation in body cavities, organs, or canals through manmade or natural orifices. It is designed for use in all types of endoscopic and endoscopic assisted procedures. The system is supplied as a Vista Stereoscope Camera Head, Vista Stereo Endoscope and a 3 D Camera control unit (CCU). The device is designed to work with commercially available light sources and video monitor overhead mounted displays. The modified coupler enables the camera head assembly to be sterilized.

F. Intended Use

The Vista StereoScope System is intended for the use in endoscopic procedures and all types of video assisted procedures, including general endoscopic and laparoscopic, thoracic, anterior and posterior spinal and as an aid in visualization of cardiac structures

G. Substantial Equivalence

The proposed modified Vista Stereoscope System is substantially equivalent to the currently legally marketed Vista Stereoscope System (K990635) in terms of intended use, operating principle, basic design, and shelf life. Testing demonstrates that the modifications proposed herein do not adversely effect safety and effectiveness.

Vista Medical Technologies

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